No. 19-2899

In the United States Court of Appeals for the Eighth Circuit

In re: Blair Hugger Forced Air Warming Devices Products Liability Litigation

GEORGE AMADOR, et al.,

Plaintiff-Appellant,

v.

3M COMPANY; ARIZANT HEALTHCARE, INC.,

Defendants-Appellees.

APPELLANT'S REPLY BRIEF - REDACTED

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

INTRODUCTION

General causation is the primary issue on appeal: whether there is reliable evidence that Bair Hugger use in ultraclean orthopedic surgery can cause periprosthetic joint infection (PJI). Plaintiffs' world-renowned experts answered "yes" based on their extensive review of published and peer-reviewed research directly addressing this question. Overwhelmingly, studies find Bair Hugger to be a vector of contamination and recommend air-free warming. It is ironic, then, that 3M brazenly champions Bair Hugger as the "most studied" patient-warming device on the market.

The centerpiece of Plaintiffs' scientific evidence is the McGovern epidemiological study. 3M dismisses it as "biased," but McGovern was peer-reviewed and published in a prestigious medical journal. Numerous studies have identified two mechanisms for McGovern's statistically-significant association. Outside of litigation, 3M concedes Bair Hugger increases risk and does so by these mechanisms. *E.g.*, A206, A217, A615, A2073. The totality of this evidence satisfies not only *Daubert* and Rule 702, but also *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986 (8th Cir. 2001).

3M contends this scientific evidence has "gaps" because it is not *conclusive*. By demanding definitive evidence as a prerequisite for

admissibility, 3M proposes a radical new legal standard that would transform Rule 702's longstanding presumption of *admissibility* into one of *exclusion*. It would further vitiate well-established scientific methodologies for causal inference, as well as *Daubert* and this Circuit's binding precedent, which universally reject scientific certainty as a threshold for admissibility.

3M's extreme proposal also runs afoul of black-letter tort law because it erroneously elevates Plaintiffs' burden of proof from a preponderance to "definitive" evidence, eviscerating the jury's role. Erecting a barrier of certainty to general-causation testimony all but forecloses product-liability litigation, particularly where, as here, it gives the manufacturer no incentive to study the safety of its product. At bottom, 3M seeks to "effectively resurrect a *Frye*-like bright-line standard for the admissibility of expert testimony." *Heller v. Shaw*, 167 F.3d 146 (3d Cir. 1999). That is not the law.

Because the MDL court abused its discretion in excluding Plaintiffs' medical experts, summary judgment must be reversed. Even if the Court affirms, it must still reverse summary judgment because the MDL court never reconsidered its *Daubert* decision admitting Dr. David's general-causation opinion. Finally, the MDL court legally erred in barring discovery

of alternative designs and improperly sealing numerous judicial records that corroborate Plaintiffs' experts' general-causation opinions.

BACKGROUND

3M claims there is no "consensus" that Bair Hugger causes PJI and that its status as the "most studied" warming device proves its safety. The published scientific literature tells a different story:

PUBLISHED STUDIES ON BAIR HUGGER	
Publication	*Salient Language*[1]
Positive Epidemiologic Studies	
McGovern 2011 (A1173)	"A *significant increase in deep joint infection*, as demonstrated by an elevated infection odds ratio (3.8, p=0.024), was identified during a period when [Bair Hugger] was used compared to a period when conductive fabric warming was used."
Negative Epidemiologic Studies	
(None)	(None)
Non-Epidemiologic Internal Contamination Studies & Papers	
Avidan 1997 (A1230)	"We conclude [Bair Huggers] are a potential *source of nosocomial infection*."

[1] All italics in this column are added emphases.

Baker 2002 (A1133)	"[T]here seems *insufficient* evidence to justify the routine use of forced air warming units … during *ultraclean orthopaedic surgery*."
Bernards 2004 (A1144)	"[T]he outbreak strain was *transmitted* by being carried on contaminated dust from *within* [Bair Hugger] to the *exterior* during operation when a fan created an air current."
Beavers 2007 (A3392)	"*Previous outbreaks* have found items such as … Bair Hugger temperature management units … to be *reservoirs of infection*."
Gjolaj 2009 (A3397)	"[A] potential disadvantage is that the [Bair Hugger] may *blow contaminated air*."
Albrecht 2009 (A1252)	"*[P]articulate emissions* from [Bair Hugger] could, conceivably, be *deposited onto the surgical site*."
Albrecht 2011 (3M.App.211)	"Fifty-eight percent of the [Bair Huggers] evaluated were internally generating and *emitting airborne contaminants*, with microorganisms detected on the internal air path surfaces of 92.3% of these blowers."
Reed 2013 (A1255)	"Swabbing detected microorganisms within 100% of the [Bair Hugger] blowers [and] … 96% of [them were] emitting significant levels of *internally generated airborne contaminants*."

Tsai 2017 (A3428)	"*Documented complications* from FAW use include an *increased incidence of surgical site infections*."
Buck 2017 (A1130)	"Bair Hugger causes an *increase in the number of particles* … in close proximity to the surgical site."
ECRI 2017 (A3401)	"A warming unit should have HEPA-grade or better air filters to reduce the risk that airborne dust, bacteria, and mold will be *blown onto the patient or into wounds*."
Lange 2019 (A3382)	"[FAW] devices … can introduce bacteria into the surgical environment, *increasing* both possible *contamination* and attributable *Surgical Site Infection (SSI) risks*."
Non-Epidemiologic Airflow-Disruption Studies & Papers	
Tumia 2002 (A3386)	"[Finding a] *rise* in the number of *colony forming units* between warmer off and warmer on."
Moretti 2009 (A3422)	"In the 20 procedures in which the Bair Hugger was used, the mean *bacterial* load values were *significantly increased*."
McGovern 2011 (A1173)	"[Bair Hugger] generated convection currents that *mobilised floor air into the surgical site area*."

Legg 2012 (A1150)	"[Bair Hugger] resulted in a significant mean increase in the temperature … and *number of particles* … over the surgical site."
Dasari 2012 (A1166)	"[Bair Hugger] generates convection current activity … [that] may *disrupt ventilation airflows* intended to clear airborne contaminants from the surgical site."
Legg 2013 (A1154)	"The convection currents *increased the particle concentration 1000-fold* ... by drawing potentially contaminated particles from below the operating table into the surgical site."
Belani 2013 (A1162)	"[Bair Hugger] was found to establish convection currents that mobilized resident *air from nonsterile areas … into the surgical site*."
Wood 2014 (A1214)	"We conclude that [Bair Hugger] *does contaminate ultra-clean air ventilation*."
He 2017 (A1183)	"[Bair Hugger] can potentially lead to surgical site *contamination in 2 ways*."
Jain 2019 (A3416)	"[Bair Huggers] were associated with substantially higher numbers of simulated particles over the operative field and *substantially higher rates of post-operative PJI*."

These publications disprove the MDL court's conclusion that *no* study has linked Bair Hugger to PJI. *See also* A872, A2070. In 1997, Avidan determined Bair Hugger is a "potential source of nosocomial infection." A1230, A3422 ("Avidan *et al.* demonstrated a higher airborne bacterial load in the air samples analysed, and a *higher incidence of nosocomial infections* in patients kept warm using Bair Hugger.") (emphasis added). In 2004, Bernards linked Bair Hugger to an outbreak of a pathogen. A1144. Both studies, published long before 2010, refute 3M's subterfuge that Plaintiffs' experts' opinions originated with Augustine. Resp.7-9.

Because "[d]ocumented complications from [Bair Hugger] use include an increased incidence of surgical site infections," A3428, scientists have determined Bair Hugger is a "reservoir[] of infection." A3392, A662. Still others urge colleagues "to NOT use [it] anymore because of its high risk for the patient to develop a surgical site infection." A2093, A3048. Even 3M's Clinical Research Director disavowed its defense, declaring, [redacted]." A217.

3M misdirects by propping up Augustine as a straw man to knock him down, Resp.7-11, but he is irrelevant to this appeal. Plaintiffs retained Drs. Samet, Jarvis, and Stonnington to evaluate the *totality* of evidence and

determine whether Bair Hugger causes PJI. A721-23, A861-62, A970. None of their reports cited Augustine's supposedly "fabricated" study. Resp.10. Nor did they rely solely on the handful of studies Augustine sponsored but did not conduct. Resp.8-9. Among the dozens of articles cited above, only *six* were supported by Augustine, and each disclosed a conflict and were published after careful peer-review by multiple independent scientists.

Given the overwhelming evidence cited by Plaintiffs' experts and presented to the MDL court, A845-58, A886-91, A978-80, additional testing was not required, although Elghobashi did so. *No* epidemiologic studies contradict—much less disprove—the significant association between Bair Hugger and PJI reported in McGovern. This combined volume of epidemiologic and non-epidemiologic data, which identifies two general-causation mechanisms, solidly supports Plaintiffs' experts' opinions.

ARGUMENT

I. The MDL court abused its discretion in reversing its initial *Daubert* order.

A. The abuse-of-discretion standard does not insulate the MDL court.

3M defends the MDL court's myriad errors of law and judgment, claiming its "gatekeeping" role and firsthand observations gave it free reign to decide questions of admissibility. This Court has warned, however, that a "range of choice" sets boundaries on a district court's discretion. *Dunn v. Nexgrill*, 636 F.3d 1049, 1055 (8th Cir. 2011). A district court abuses its discretion when it: (1) is influenced by a mistake of law, (2) fails to consider a relevant factor, (3) gives significant weight to an irrelevant or improper factor, *or* (4) improperly weighs relevant factors. *Id*.

Rule 702's strong presumption of admissibility further circumscribes the district court's choices in evaluating expert testimony. As this Court explained when reversing the *same* district court:

> The liberalization of the standard for admission of expert testimony creates an intriguing juxtaposition with our oft-repeated abuse-of-discretion standard of review. While we adhere to this discretionary standard for review of the district court's Rule 702 gatekeeping decision, *cases are legion* that, correctly, under *Daubert*, call for the *liberal admission of expert testimony*.

Johnson v. Mead Johnson, 754 F.3d 557, 562 (8th Cir. 2014) (emphasis added). Given Rule 702's strong presumption of admissibility, exclusion of expert testimony is permissible only where, unlike here, "it is so fundamentally unsupported that it can offer no assistance to the jury." *Id.* (cleaned up).

3M maintains *Glastetter* discarded this longstanding rule in favor of a stricter standard. *Au contraire*. That specific-causation decision affirmed the exclusion of an expert's differential diagnosis as "scientifically invalid" because there was *no* evidence to support the premise that Parlodel could cause vasoconstriction, much less plaintiff's stroke. 252 F.3d at 989-90.

This Court has *never* interpreted *Glastetter* as imposing a heightened standard. And rightly so: a "scientifically invalid" opinion is *ipso facto* "fundamentally unsupported." Tellingly, this Court has repeatedly cited *Glastetter* when evaluating whether expert testimony is "fundamentally unsupported." *Bonner v. ISP*, 259 F.3d 924, 929-30 (8th Cir. 2001); A2094.

What's more, this Court has applied that permissive standard to expert testimony in over 30 cases since *Glastetter*. *E.g.*, *Klingenberg v. Vulcan Ladder*, 936 F.3d 824, 830 (8th Cir. 2019); *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 614 (8th Cir. 2011). And scores of decisions reverse trial courts for abusing their discretion in excluding causation testimony, just like here.

Johnson, 754 F.3d at 564; *Hill v. Sw. Energy*, 858 F.3d 481, 486-87 (8th Cir. 2017); *Kuhn v. Wyeth*, 686 F.3d 618, 627-28 (8th Cir. 2012); *Smith v. BMW*, 308 F.3d 913, 919-21 (8th Cir. 2002); *Lauzon v. Senco*, 270 F.3d 681, 694-95 (8th Cir. 2001); *Jenson v. Eveleth*, 130 F.3d 1287, 1297 & n.15 (8th Cir. 1997).

Ignoring those decisions, 3M cites *Wholesale Grocery* to suggest admissibility rulings are rarely reversible. Resp.19-20. That was an antitrust case where this Court recognized *Daubert*'s presumption of admissibility and held the trial court appropriately examined the expert's *methodology* rather than the *correctness* of his opinion. *In re Wholesale Grocery Prods. Antitrust Litig.*, 946 F.3d 995, 1001-02 (8th Cir. 2019). But the expert's methodology did not support plaintiffs' claims for an obvious reason: its data and assumptions failed to address the *relevant* damages question. *Id.*

Likewise, in *Wagner v. Hesston*, 450 F.3d 756 (8th Cir. 2006), this Court affirmed the exclusion of plaintiff's experts because the testing was undocumented, conducted two decades earlier in another case, and had not been peer-reviewed. *Id.* at 758-59. And in *National Bank of Commerce v. Associated Milk Producers*, 191 F.3d 858 (8th Cir. 1999), the expert failed to cite any published literature correlating the toxin to the injury. *Id.* at 863-64.

None of those cases justifies the MDL court's anomalistic departure from *Daubert*, Rule 702, and this Court's binding precedent. The causation opinions of Plaintiffs' experts rest on robust and relevant scientific evidence that *directly* addresses Bair Hugger's effect on operating-room contamination and infection. In stark contrast to *Wholesale Grocery*, the MDL court relied on its own flawed assessment of the correctness of the experts' opinions, rather than the reliability of their methodology. This was an abuse of discretion. *See Johnson*, 754 F.3d at 562; *Dunn*, 636 F.3d at 1055.

3M avers the MDL court's "firsthand" observation of the experts' evidence allowed it to jettison their opinions. This is a ruse. Plaintiffs' experts presented no new or different evidence of general causation at trial than offered in prior *Daubert* proceedings.[2] To the extent the court made credibility determinations—which it no doubt did—it did so in error. The jury "should be the one to decide among the conflicting views of different experts." *Johnson*, 754 F.3d at 564.

[2] The only "new" evidence is Jeans, which 3M invoked months *after* trial. Still, Jeans did not analyze the relevant device (Bair Hugger) or injury (PJI).

B. The MDL court erred in misapplying *Joiner* and *Glastetter*.

3M defends the MDL court's reconsideration ruling, arguing *Joiner* abandoned *Daubert*'s bright line between methodology and conclusions. Not so. *Joiner* stands for the unremarkable proposition that an expert opinion is unreliable if none of the underlying evidence fits the expert's conclusions. *Gen. Elec. v. Joiner*, 522 U.S. 136, 146 (1997). In both *Joiner* and *Glastetter*, the cited studies had obvious "gaps" because they analyzed the *wrong* correlations: the associations applied to *different* toxins or *unrelated* injuries—or involved *dissimilar* populations—making extrapolation wholly unreliable. *Joiner*, 522 U.S. at 144-46; *Glastetter*, 252 F.3d at 989-90.

No such gaps exist here. McGovern found Bair Hugger significantly increases risk of PJI—the relevant outcome—and other experimental evidence has pinpointed the precise mechanisms for how Bair Hugger does so. *E.g.*, A729-43. Had McGovern linked Bair Hugger to higher surgical complication rates in general, but not PJI, *Joiner* and *Glastetter* might apply.

In sum, neither *Joiner* nor *Glastetter* requires each study to provide conclusive evidence of causation—just *relevant* evidence of it. In misreading both decisions, the MDL court abused its discretion. *Dunn*, 636 F.3d at 1055.

C. The "gaps" perceived by the MDL court were of its own making.

1. The MDL court abused its discretion in concluding McGovern did not support Plaintiffs' experts' opinions.

The McGovern study included two components: (1) an epidemiologic analysis of PJI rates in patients receiving Bair Hugger versus conductive warming in orthopedic surgery; and (2) a mechanistic analysis comparing the effects of each blanket on operating-room airflow. A1173-79. The epidemiologic analysis found a **statistically-significant 380% increased risk of PJI in Bair Hugger patients** compared to conductive-warming patients. A1173. The mechanistic analysis found Bair Hugger "generated convection currents that mobilised floor air into the surgical site area," but "[c]onductive fabric warming had no such effect." *Id*. McGovern concluded this evidence "offers a plausible explanation for the significant association between the patient warming device and [PJI] risks." A1178.

McGovern provides reliable epidemiologic and mechanistic evidence that Bair Hugger increases PJI. It was peer-reviewed and published pre-litigation, contains error rates, and employs well-established scientific methods. McGovern therefore satisfies both the standards *Daubert* deemed

reliable, 509 U.S. at 592-95, as well as 3M's primary authority, *Glastetter*, 252 F.3d at 992 (epidemiologic studies are "much desired" by litigants).

On appeal, 3M wages the same meretricious attacks on McGovern that it did below. The MDL court correctly rejected these arguments in its initial *Daubert* order. Citing controlling precedent, the court held Plaintiffs' experts could rely on McGovern and mechanistic evidence explaining the strong statistical association between Bair Hugger and PJI. Add.61-62.

On reconsideration, however, the MDL court abruptly reversed itself. Though it still found McGovern "reliable," Add.37, the court inexplicably barred Plaintiffs' experts from relying on McGovern because it showed only an association. Add.38. Citing foreign cases, the court declared—as 3M does—that McGovern's failure to "prove[]" causation was a "gap" that made Plaintiffs' experts' opinions unreliable. Add.38-40. This was error.

Both 3M and the MDL court conflated the statistical concept of "association" with the epidemiological concept of "causation"—a *judgment* scientists make after considering statistical correlations combined with other scientific evidence. By definition, epidemiologic studies can show only an association between exposure and outcomes. REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 552, 598 (3d ed. 2001) [hereinafter "REFERENCE

MANUAL"]. Because "[e]pidemiology cannot prove causation," "causation is a judgment" for scientists who interpret the data. *Id*. at 598. That is why the McGovern authors stated their study was limited to establishing an association. A1179. The MDL court's ignorance of this textbook teaching was an abuse of discretion. *See Dunn*, 636 F.3d at 1055.

The MDL court erred in imposing a newfangled rule that an expert's causation opinion must rest on studies stating their results definitively *prove* causation. Add.38; Resp.22. This Court has flatly rejected that stratospheric standard: "Neither Rule 702 nor *Daubert* requires that an expert opinion resolve an ultimate issue of fact to a scientific absolute in order to be admissible." *Bonner*, 259 F.3d at 929; *Adams v. Toyota Motor*, 867 F.3d 903, 916 (8th Cir. 2017). The failure of individual studies to provide "perfect" evidence of causation does not invalidate an expert's opinion, especially where they provide "useful information." *Kuhn*, 686 F.3d at 632; *Daubert*, 509 U.S. at 590 (it is "unreasonable to conclude that the subject of scientific testimony must be known to a certainty"); *Hill*, 858 F.3d at 486 (abuse of discretion to exclude testimony not based on "perfect" evidence).[3]

[3] Citing no binding cases requiring definitive evidence, 3M cites cases from "other circuits" that violate this Court's precedent. Resp.22; A3472-75.

Plaintiffs' burden is to establish the admissibility of their experts' testimony by a "preponderance of the evidence." *Lauzon*, 270 F.3d at 686. The MDL court's demand for *definitive* proof as a threshold for admissibility erroneously elevates the burden of proof and flouts this Circuit's presumption that testimony should be admitted unless "it is *so fundamentally unsupported* that it can offer *no assistance* to the jury." *Johnson*, 754 F.3d at 562 (emphasis added); *Lauzon*, 270 F.3d at 696 (error to exclude opinion because doing so "fell outside [Rule 702's] spirit of admissibility").

Citing the Reference Manual, 3M claims for the first time that a single epidemiologic study requires replication from *several* epidemiologic studies before it is "accepted" as proving causation. Resp.26-28. Properly understood, the cited snippets make clear that epidemiologic studies show associations, not causation. REFERENCE MANUAL at 552. Assessing whether the association is *causal* requires understanding "how the study findings fit with other scientific knowledge." *Id*. at 552-53. Replicability is only one of several non-dispositive Bradford-Hill factors for causal inference, and there is no rigid formula for applying them. *Id*. at 600 ("One or more factors may

be absent even when a true causal relationship exists."). Contrary to 3M's argument, then, "replicability" is not "the legal standard." *Id*. at 604 n.163.[4]

3M also claims the Manual requires epidemiologic evidence to satisfy three conjunctive conditions. Resp.26-27. Quite the opposite. The cited passage states an epidemiologic study is "good evidence" of causation under *any* of these "circumstances." REFERENCE MANUAL at 221. Glaringly, 3M omits key language from the third circumstance, which states "there is a plausible explanation for the effect of the independent variable." *Id*. Besides McGovern, Plaintiffs' experts cited studies identifying two plausible mechanisms for the association between Bair Hugger and PJI.

Thus, the Manual does not require multiple epidemiologic studies. As 3M conceded below, A3445, there is *no* requirement that *any* epidemiologic studies support a causation opinion. *Bonner*, 259 F.3d at 929; REFERENCE MANUAL at 609 n.180 ("In many instances, causation can be established without epidemiologic evidence."); *Glastetter*, 252 F.3d at 992 ("The absence of epidemiological evidence did not doom [the] case."). The MDL court

[4] 3M does not dispute the court erred in excluding Samet without proper notice. Resp.42n.8; *Heisler v. Metro. Council*, 339 F.3d 622, 631 (8th Cir. 2003).

erred in concluding McGovern's failure to *prove* causation created a "gap" in Plaintiffs' experts' opinions. *See Dunn*, 636 F.3d at 1055.

2. The MDL court abused its discretion in concluding Plaintiffs' experts never considered "potential" confounders.

The MDL court also wrongly concluded Plaintiffs' experts "failed to consider alternative explanations." Add.34. Both Samet and Jarvis meticulously analyzed whether the antibiotic and antithrombotic—the *only* "potential confounders" in McGovern—confounded the association. A731-32, A1345, A1422-26, A1481, A3684. The MDL court recognized this, Add.41n.23, yet 3M makes no attempt to shore up the court's internally inconsistent rulings. A2078, A3484-94; Add.61.

Instead, 3M belabors "background risk," confusing general and specific causation. Resp.34. Alternative causes of a specific patient's infection—*e.g.*, bacteria from a patient's skin—are irrelevant to the general-causation question of whether Bair Hugger can *also* cause PJI. REFERENCE MANUAL at 623, 627; A3476-78. That is why Samet used the sufficient-component-cause methodology—which 3M readily admits is reliable, A3432—to conclude Bair Hugger is "an additional cause" of PJI. A728.

The MDL court conceded Plaintiffs' experts analyzed *all* the potential confounders identified in McGovern, Add.41n.23, but excluded them anyway because they "never mentioned—let alone investigated"—MSSA screening, which was *not* identified in McGovern as a potential confounder. Resp.35. This is baffling. It is undisputed Samet and Jarvis *did* analyze that irrelevant variable both before and after Jeans was published in 2018.

Before Jeans, Samet addressed "unidentified" confounders in his report. A732. He testified they did not confound McGovern. A1356, A1425-26, A3659. In fact, no "published literature" suggested MSSA screening impacts PJI. A1444. Jarvis testified that 3M's own expert proved MSSA screening is irrelevant to PJI.[5] A1536. Unsurprisingly, then, *none* of the McGovern authors "acknowledged" MSSA screening confounded the association between Bair Hugger and PJI. Opening40-41; Add.41-44.

After Jeans, Plaintiffs moved to supplement their expert reports. A3584-85. The court denied the motion, A3041, A3381n.2, but allowed affidavits from Samet and Jarvis after reconsideration briefing closed.

[5] 3M's experts agreed the *only* evidence on MSSA screening involved *wound* infection, not the injury here (PJI). A3449, A3434, A3498-99.

A3659-61. Both affidavits analyzed Jeans and *again* concluded MSSA screening was a red herring. A1106-1107, A1109-13, A3655-63.

The MDL court's conclusion that Plaintiffs' experts "never mentioned—let alone investigated"—MSSA screening collapses on this uncontested record. Add.42. The court refused to consider those opinions, Plaintiffs' additional arguments distinguishing Jeans, A3620-28, A2011-19, A2081-85, and published studies post-Jeans that corroborate McGovern's findings. A3416. The court even disregarded 3M's expert's testimony that *Bair Hugger* may have confounded Jeans, A2081, as Jeans *itself* concedes. A1227 ("[The] improvement in [wound] infection rates [from MSSA screening] could have been [due] to other factors.").[6]

This case bears no resemblance to *Sorenson* or *Norris*, where experts "completed ignored" contrary evidence. Resp.35-36. Here, the MDL court—not Plaintiffs' experts—so erred. *E.g.*, *Johnson*, 754 F.3d at 563 (reversing same court because "experts are not required to rule out all possible

[6] Assuming Plaintiffs' experts never "mentioned" Jeans, it was still error to exclude them because Jeans found an association only in hips, A1227, not knees, which totaled over half the MDL cases. A3625, A3661-64.

causes"); *Seamon v. Remington Arms*, 813 F.3d 983, 989 (11th Cir. 2016) (reversing because expert "did in fact" consider alternative causes).

3. The MDL court abused its discretion in requiring mechanistic evidence to prove causation.

Mechanistic evidence is not always necessary to support causal inference. *Daubert v. Merrell Dow Pharms.* (*Daubert II*), 43 F.3d 1311, 1314 (9th Cir. 1995). But when it exists, such evidence "lends credence to an inference of causality," especially when combined with epidemiologic evidence. REFERENCE MANUAL at 604, 609 n.180. Plaintiffs' experts identified two biologically plausible mechanisms of general causation to support the statistical association McGovern found between Bair Hugger and PJI.

Instead of treating this evidence as one component of the experts' opinions—as scientific methodology requires—the MDL court isolated the studies and claimed each one's inability to prove causation constituted a "gap." Add.25-41. The court erred in conflating *mechanism* with *causation* and atomizing the evidence. Opening46-47. The court's actions speak louder than its words. Giving lip service to a holistic approach, it did the opposite in holding Plaintiffs' experts could not rely on McGovern, the published

mechanistic studies, or Elghobashi's CFD because each piece of evidence *by itself* did not *prove* causation. Add.29-32, Add.35, Add.38.

3M suggests the Manual gives judges "broad discretion" to atomize evidence. Resp.40-41. The Manual makes clear, however, that doing so is inimical to scientific methodology. REFERENCE MANUAL at 19-20. And if a court does a piecemeal analysis, it cannot decide whether the inferences drawn from each source are correct. *Johnson*, 754 F.3d at 562.

a. No gaps exist in the internal-contamination mechanism.

The MDL court ignored studies, documents, and testimony demonstrating the internal-contamination mechanism. 3M follows suit in disregarding Bernards, which reported an "outbreak strain [of bacteria] was transmitted by being carried on contaminated dust from within [Bair Hugger] to the exterior." A1144, A1957. Bernards also uncovered the *identical* mechanism endorsed by Plaintiffs' experts: "Bair Hugger is designed to create an airflow; dust is sucked into the machine, with filters becoming contaminated and possibly serving as a secondary source of transmission."[7] A1144, A871, A974, A736. Bernards closes any "blanket gap"

[7] The same mechanism prompted the CDC's Director to warn, "Nothing that blows air should be in an operating theater." A883.

or "surgical-site gap." Resp.23; 3M.App.217 ("[Bernards] implicated FAW blowers as the causative factor in an outbreak."); A3392.

Even 3M's experts agree this is a plausible mechanism of causation. When asked whether he believed "infectious microbes being harbored in a Bair Hugger unit can create a risk of infection," Dr. Borak answered, "[I]t seems reasonable that it could." A2069 (citing A3433). Yet the MDL court and 3M disregarded this dispositive evidence. *Id.*, A1956-57.

Unable to challenge this admission, 3M surmises Bair Hugger's *hose* discharges bacteria, A569, but the *blanket* does not. This blinks reality. A1690(286:20-24). 3M agrees [redacted]." A305, A3917-18. Studies also prove blankets are "not designed to act as a microbial filter," A1132, do not in fact filter bacteria, A3426-28, and should not be used in "ultraclean orthopedic surgery." A1133; *see also* A595, A872, A976, A1560, A2071. Indeed, despite "insensitive" blanket testing, A1132, Avidan found Bair Huggers "are a potential source of nosocomial infection" because they harbor pathogens. A1230-32. Yet again, the court ignored this evidence and recent findings of

"increase[d] patient infection risk" given correlations between internal and airborne contamination.[8] A2070, A3379-83.

3M concedes "every single study indicates that Bair Hugger increases the particle count over the sterile field." A536, A2073. 3M also agrees—as did the MDL court, A1971—particles equate to bacteria. A306. 3M nevertheless claims that none of Plaintiffs' evidence "addresses particles large enough to carry bacteria." Resp.24. Nonsense. Reed found Bair Hugger allows "larger ambient airborne contaminants [to] pass through the intake filter," A1259, and Buck found 10-micron particles exit the *blanket*. A1129. Those particles are indisputably large enough to carry bacteria, A3402-08, A1209, A150-10, A1559, A1624, as the MDL court itself concluded in rejecting 3M's identical argument. Add.60; A2075.

Despite that uncontested ruling, 3M claims none of Plaintiffs' experts relied on Buck. Resp.24n.3. That is patently false, *e.g.*, A1493-95, as is 3M's claim that bacteria cannot reach the surgical site. A3422 ("bacterial load values were significantly increased" at the surgical site), A1217-20 (Bair Hugger "contaminate[s] ultra-clean air ventilation"), A3401.

[8] 3M claims Albrecht "never" found bacteria, but the cited document contradicts its argument. 3M.App.229 (finding "few CFUs," not none).

Thus, just as 3M's Director of Clinical Research opined [redacted], A217, Plaintiffs' experts should be allowed to opine that this infection risk "is not just theoretical." A872, A869-70, A873-74, A973-76, A733-36, A1080-84, A2070. The risk is real, and the MDL court must be reversed on appeal. *See*, *e.g.*, *Kennedy v. Collagen*, 161 F.3d 1226, 1230 (9th Cir. 1998) (reversing because "[t]he court did not consider all of the data"); *Seamon*, 813 F.3d at 990-91 (reversing because court "mischaracterized" opinion as "speculation" despite "facts in the record").

b. No gaps exist in the airflow-disruption mechanism.

The MDL court also abused its discretion by concocting "gaps" in the airflow-disruption mechanism, another well-described explanation for Bair Hugger's association with PJI. A733-35, A870-72, A975-76, A984-86.

3M highlights the court's error in positing that none of these mechanistic studies "found causation." Resp.29. This tautological argument defies logic. Mechanistic studies alone do not and ultimately cannot prove causation; but combined with other evidence, they may support causal inferences. REFERENCE MANUAL at 20, 604, 609 n.180, 647. Plaintiffs' experts properly considered airflow-disruption studies together with epidemiologic evidence in reaching their general-causation opinions.

Besides conflating mechanism and causation, 3M dismisses these published studies because Augustine purportedly funded them. Resp.29. On the contrary, neither Legg study was funded by Augustine. A1150-57. Nor was Jain, which unequivocally proclaimed Bair Hugger is associated with "substantially higher rates of post-operative PJI." A3416. Regardless, the MDL court found *all* these studies reliable. Add.31.

3M weakly attempts to defend the court's paradoxical assertion that these studies were not "real world." Opening52-54. But 3M's CFD expert used a nearly identical set-up, A1642, and all the studies occurred in real operating rooms. A1150, A1154, A1160, A1167, A1174. Some even tracked staff movement, A1170, despite the court's contrary assertion. Add.34.

3M parrots the MDL court's mistaken assumption that "no study shows that Bair Hugger has any impact on *particles* that are large enough to carry bacteria." Resp.29 (emphasis added). Even if true—and it is not—Moretti found "mean *bacterial* load values were significantly increased" from Bair Hugger. A3422, A1217. Plaintiffs' experts cited Moretti, A873, A1375, A1443, along with Tumia's finding that bacteria "went up" with Bair Hugger. A3920. 3M concedes these studies show Bair Hugger increases

bacteria, *e.g.*, A3385, but the MDL court *again* ignored both of them along with 3M's [redacted]." A626, A2091, A2024.

Moreover, Legg 2012 found Bair Hugger significantly increased 5-micron particles, A1150, while Legg 2013, McGovern, and Belani all found Bair Hugger transported massive, 4-millimeter (4,000-micron) particles to the surgical field. A1155, A1173, A1159. Stocks and Darouiche prove that much *smaller* particles of 5-micron and 10-microns "*each*" carry bacteria, A1209, A3406-07, Add.58, as Jarvis repeatedly made clear. A875, A1507-10, A1624. The MDL court erred in mischaracterizing all these studies as well as Jarvis' testimony.[9] Even 3M's expert conceded Bair Hugger transports unsterile particles to the surgical field. A3718.

All told, any so-called "gaps" in the airflow-disruption mechanism were of the court's own making. Multiple studies conclude this mechanism increases "contamination at the surgical site." A1217, A3423, A3416, A1173,

[9] 3M claims Jarvis "reinterpret[ed] [Stocks] in a way that the study's authors did not." Resp.29. Stocks found 5-micron particles carry bacteria. A1209; 3M.App.427(753:21-754:7). Jarvis thus testified he was "not saying something that the authors did not say." 3M.App.427(754:16-25), 3M.App.429(755:21-758:13). 3M also claims Jarvis agreed that only Elghobashi's CFD involved particles large enough to carry bacteria, even though the transcript it cites belies this argument. 3M.App.433(761:20-22).

A1150, A1166, A1154, A1162, A1182. This not only "lends credence to an inference of causality," but it is "good evidence" of causation when combined with epidemiological data. REFERENCE MANUAL at 604.

c. No gaps exist in Elghobashi's CFD.

Elghobashi's CFD also proves Bair Hugger transports 10-micron particles to the sterile field. A1042-44, A1182. Below, 3M "conceded that ten-micron particles can be dangerous" and that Elghobashi's analysis of Bair Hugger "in a model operating room by large-eddy simulation" is "reliable." Add.58. Even the MDL court concluded "Elghobashi simulate[d], using *accepted physical principles*, how the Bair Hugger could *convect squames to the surgical wound*." Add.61 (emphasis added).

Flailing to defend the MDL court's opposite conclusion on reconsideration that Elghobashi "never tested this theory," Add.13, 3M claims Elghobashi's trial testimony constitutes "new" evidence. Resp.15, 30. 3M is wrong. Elghobashi's CFD was conducted in a real operating room with a patient, tables, surgical lamps, and four surgeons; it *never* analyzed staff or door movement. A989, A1185. And for good reason. A1024, A1631. As other scientists have repeatedly determined, those variables would only "magnify" or "aid" Bair Hugger's impact. A1161, A1178, A3606.

The fact that those variables also disrupt airflow may be relevant to *specific* causation as factors to rule *out*; hence 3M's citation to trial testimony. Resp.30-31. But Elghobashi's opinions were confined to *general* causation: whether Bair Hugger can be ruled *in* as "transporting squame particles to the surgical site." A988-89, A728, A1629. To answer that question, Elghobashi properly "isolated the effect of the Bair Hugger," A1630, as other published studies did before him, A1151, A1154, A1184, A1683-84, A1697, and as 3M's own expert did. A1642, A1661, A1611(178:18-22);[10] *see Shuck v. CNH Am.*, 498 F.3d 868, 874 (8th Cir. 2007) ("[I]t is disingenuous to challenge an opponent's use of [the same] methodology."); *Adams v. Lab. Corp.*, 760 F.3d 1322, 1330 (11th Cir. 2014) (reversing for same reason). Elghobashi's CFD was thus no less "reliable" on reconsideration than when the MDL court initially and correctly admitted it. Add.58, Add.61. *See In re Zurn*, 644 F.3d at 614 (CFD should not be excluded even where, unlike here, inputs are flawed); *Lauzon*, 270 F.3d at 695 (similar).

The *only* new evidence Elghobashi presented to the MDL court increased, not decreased, his study's reliability. In 2017, Elghobashi's CFD

[10] Like Elghobashi, 3M's CFD expert did not model staff or door movement. A1642, A3438.

was peer-reviewed and published, A1182, proving it "meets at least the minimal criteria of good science." *Daubert II*, 43 F.3d at 1318. Still, 3M claims the MDL court found the CFD unreliable because it was "made-for-litigation," Resp.32, even though numerous scientists have cited the CFD since its publication. A3416. Regardless, weighing bias is a job for the jury, not the judge. *See Adams*, 760 F.3d at 1333 ("The risk of bias would mean, at most, that [expert] testimony is to some extent 'shaky,' and shakiness goes to the weight of [the] testimony, not its admissibility.").

In short, no "gap" existed in Elghobashi's opinion because his CFD tested Bair Hugger and *directly* proved his general-causation hypothesis: Bair Hugger can cause 10-micron-sized particles to reach the sterile surgical field. A988-90, A1042-44, A1629. That other potential mechanisms can *also* do so is irrelevant at this *general-causation* stage. *Junk v. Terminix*, 628 F.3d 439, 450 (8th Cir. 2010). The MDL court's confusion of this rudimentary legal distinction was an abuse of discretion. *See Dunn*, 636 F.3d at 1055.

D. The MDL court abused its discretion in finding an alleged lack of general acceptance of Plaintiffs' experts' conclusions.

On reconsideration, the MDL court accepted 3M's argument that Plaintiffs' general-causation opinions were unreliable because they have

been "universally" rejected. Resp.18, 36. That is false. Were it true, none of the studies finding Bair Hugger increases contamination and infection would ever have been published. To date, *no one* in the scientific community has repudiated these studies or called for their retraction. Nor are there any *contrary* studies refuting the results of this body of research.

Under *Daubert*, general acceptance is one nondispositive factor, and it focuses on whether the expert's *methodology*—not *conclusions*—has gained support. *Daubert*, 509 U.S. at 594-95. The MDL court erred by misapplying this factor to the experts' ultimate conclusions—rather than their methodologies—and ignoring the remaining *Daubert* factors. *Id*. The court began and ended its analysis with "general acceptance," noting at the outset that an alleged lack of consensus "presents a challenge" for Plaintiffs' experts, Add.25, and concluding that an alleged lack of acceptance of their *conclusions* constituted "too great an analytical gap." Add.46-47. This was another reversible error. *See Dunn*, 636 F.3d at 1055; *Milward v. Acuity Specialty Prods.*, 639 F.3d 11, 22 (1st Cir. 2011).

The MDL court compounded this error by again ignoring contrary evidence cited by Plaintiffs and instead favoring 3M's litigation-driven evidence. In so doing, it "crossed the boundary between gatekeeper and trier

of fact." *Milward*, 639 F.3d at 22. For instance, the court touted the ICM while refusing to consider evidence that 3M influenced and edited those findings during litigation, A1891, A3866n.19; the ICM did not review even close to the same data Plaintiffs' experts did, A2090-91, A217, A2088-89; and the ICM recognized the "theoretical risk" of forced-air warming. 3M.App.352. Worse, 3M's Medical Director admitted the ICM is not "evidence based," A615, but the court predicated its *Daubert* ruling on it.[11]

The court also refused to credit published statements that Bair Hugger increases infection risk. A1230, A1144, A2092, A2070, A3380-81. And it declined to consider 3M's documents acknowledging [redacted]. A3049n.24; Add.46n.27. One organization "issued a recommendation NOT to use forced-air warming anymore because of its high risk of the patient to develop a surgical site infection." A2093, A3048, A3440. "Renowned" surgeons also reject Bair Hugger, A191, because it allows "contaminated air particles [to] bypass[] the filtration system and mak[e] contact with the patient," A3442, and it

[11] 3M also cites nonprofits like ECRI but omits their updated guidance that Bair Hugger "should have HEPA-grade or better air filters to reduce the risk that airborne dust, bacteria, and mold will be blown onto the patient or into wounds." A3401. The other articles are no better. A3804-10.

"contribute[s] to post-op wound infections because of the circulating air," A662—the *same* mechanisms Plaintiffs' experts cited.

Internally, 3M [redacted]

A662. On appeal, however, 3M calls this evidence "illusory." Resp.38. The only illusion is 3M's blatant misrepresentation that "the groups Plaintiffs identify do not exist," which its own documents contradict, *e.g.*, A191, A2093, and 3M's *ipse dixit* that those damning documents are "irrelevant." Resp.38. The MDL court's failure to review that evidence does not make it irrelevant. It does, though, show a grave abuse of discretion.[12] *Dunn*, 636 F.3d at 1055; *Kennedy*, 161 F.3d at 1230; *Seamon*, 813 F.3d at 989.

The court also disregarded 3M's own admissions. Before this MDL, 3M executives conceded [redacted]" A217. Other 3M documents recognize physicians' [redacted]

[12] The court also refused to consider additional evidence of general acceptance, A3049n.24, including that every FAW manufacturer other than 3M warns about "airborne contamination" risks. *E.g.*, A619, A3924. That other manufacturers warn of this exact risk proves no "gap" exists.

[redacted]," A197, A237, and that [redacted]. A206, A247, A2024, A2091, A3633.

This Circuit has repeatedly warned that district courts cannot take sides on competing theories where—as here—there is legitimate debate. *E.g.*, *Kuhn*, 686 F.3d at 625. The volume of evidence the MDL court ignored shows there is significant room on both sides of this debate. *Johnson*, 754 F.3d at 564. As in *Johnson*, the same court again abused its discretion in siding with a party on a question that the jury, not a judge, must resolve.

* * * * *

In summary, the MDL court strayed far outside its range of discretion. It abused its discretion in four ways. *See Dunn*, 636 F.3d at 505.

First*, *numerous errors of law influenced the court's reconsideration ruling, including:

- Misinterpreting *Joiner* and *Glastetter* to hold McGovern's findings constituted a fatal "gap" for failing to prove causation;
- Mischaracterizing Rule 702 as requiring absolute certainty;
- Requiring each component of expert testimony to prove causation;
- Confusing general and specific causation;
- Misapplying *Daubert II* to exclude Elghobashi's published CFD;
- Misunderstanding *Daubert's* general-acceptance factor; and
- Repeating the same errors it made in *Johnson* by resolving doubts in favor of exclusion and relying on its own assessment of the correctness of the experts' opinions.

Second, the court failed to consider relevant factors by:

- Ignoring evidence that Plaintiffs' experts considered confounders;
- Disregarding research confirming Bair Hugger increases PJI; and
- Failing to consider all the *Daubert* factors.

Third, the court gave significant weight to irrelevant factors by:

- Conflating association with causation; and
- Erroneously assuming MSSA screening confounded McGovern.

Fourth, the court committed errors in judgment by:

- Ignoring Plaintiffs' experts' testimony on confounders;
- Misinterpreting the Jeans study;
- Mischaracterizing Jarvis's testimony on particles and bacteria; and
- Misunderstanding Elghobashi's hypothesis and testing and attacking the credibility of his conclusions.

Given the scope and gravity of these errors, 3M cannot defend them as harmless. The MDL court's repeated violations of controlling legal and scientific standards deprived thousands of injured plaintiffs of their right to a jury and a remedy. Its exclusion of Plaintiffs' experts requires reversal.

II. The MDL court erred in granting summary judgment because it ignored other expert testimony and 3M admissions about causation.

Because Plaintiffs' experts' testimony is admissible and creates a triable issue on causation, this Court should reverse summary judgment. *Kuhn*, 686 F.3d at 633. Even if the Court affirms exclusion despite *Daubert*'s "call for the liberal admission of expert testimony," *Johnson*, 754 F.3d at 562, it must still reverse summary judgment. 3M says the reconsideration ruling eliminated all of Plaintiffs' "general-causation experts," Resp.45, but the MDL court *never* reconsidered its order admitting Dr. David's general-causation opinion. Add.65. Nor did 3M ever request such relief. A3582-83.

David conducted a "hazard analysis and risk assessment" of Bair Hugger, A1058, by examining it, A1063-69, reviewing its "troubling regulatory history," A1070-80, analyzing literature linking it to PJI, A1080-84, and evaluating 3M's "refusal to mitigate" that risk. A1084-96. David also identified both mechanisms, A1060-61, opining Bair Hugger is "more likely than not contributing to infections during orthopedic implant surgeries." A1054, A1061, A1097-98. 3M nevertheless contends Plaintiffs "admitted" that "the opinions of some of their non-medical experts" were not offered

for causation. Resp.49 (citing A2760(419:2-5)). False. Although Buck and Koenigshofer did not opine about causation testimony, David did. A1098.

Because David's general-causation opinion remains intact, 3M cries "waiver," alleging Plaintiffs "never argued" they could survive summary judgment with other experts. Resp.49. 3M's argument is a *non sequitur*.

First, Plaintiffs preserved this argument when opposing summary judgment. A3551-52 ("other types of expert testimony" besides medical-expert testimony supports general causation). Second, 3M never moved for reconsideration on that ground. Third, not a shred of "new" evidence touched—much less doomed—David's opinions. *Id.* 3M, not Plaintiffs, fumbled in overlooking that dispositive causation testimony.

3M also assails Plaintiffs for supposedly not citing legal authority that non-medical experts may express general-causation opinions. Resp.49. But "[c]ommon sense dictates" that non-medical experts like David can testify about general causation. 39 A.L.R. 7th Art. 8 (2018); *Loudermill v. Dow Chem.*, 863 F.2d 566, 569-70 (8th Cir. 1988); *Gideon v. Johns-Manville*, 761 F.2d 1129, 1136 (5th Cir. 1985); *Genty v. Resolution Tr.*, 937 F.2d 899, 917 (3d Cir. 1991); *Monroe v. Zimmer*, 766 F.Supp.2d 1012, 1024 (E.D. Cal. 2011).

These decisions reflect the reality that "[m]any non-medical doctors work in the field of medical product design and development" and are therefore qualified to testify about related risks. *Johnson v. Zimmer*, 2004 WL 742038, at *6 (D. Minn. Mar. 31, 2004). 3M itself proffered several non-medical experts to opine about general causation. *E.g.*, A3454. It is hypocritical to suggest that David—a preeminent bioengineer with expertise in evaluating medical devices, A1056-57—cannot do the same.

3M unsuccessfully downplays the admissions of its own officials. Resp.48. *Glastetter* never held corporate admissions cannot support general causation; it merely found the statements there were not in fact admissions on causation. 252 F.3d at 991. *Vallejo* fares no better. There, low-level employees could not make binding corporate admissions. *Vallejo v. Amgen*, 903 F.3d 733, 747 (8th Cir. 2018). Here, 3M's Clinical Research Director and corporate witness admitted [redacted] A217. It is hard to fathom a more binding admission.

Accordingly, even if this Court affirms the exclusion of Plaintiffs' medical experts, the summary judgment decision still requires reversal.

III. The MDL court legally erred in prohibiting discovery of safer alternative designs.

The MDL court also erred in barring Plaintiffs from discovery of conductive devices without a state-by-state analysis of alternative-design requirements. Though the court "caution[ed] [3M] against relying too heavily on [its] discovery order," A2260-61, 3M claims "no authority" permits a "different product" to qualify as an alternative design. Resp.54. Besides 3M's agreement that "air-free" warming is an ideal "alternative to Bair Hugger," A186, the laws of numerous states defeat 3M's argument. *E.g.*, *LaBelle v. Philip Morris*, 243 F.Supp.2d 508, 521-22 (D.S.C. 2001) ("entirely new and separate species" qualified as alternative design); *Little v. Brown & Williamson Tobacco*, 243 F.Supp.2d 480, 495n.19 (D.S.C. 2001).

IV. The MDL court improperly sealed numerous judicial records that corroborate Plaintiffs' experts' general-causation opinions.

Finally, the MDL court violated *IDT Corp. v. eBay*, 709 F.3d 1220 (8th Cir. 2013), by sealing dozens of judicial records illuminating 3M's knowledge that Bair Hugger [redacted]. *E.g.*, A217.

CONCLUSION

The MDL court's about-face in granting reconsideration and tossing over 5,000 cases was not a rational exercise of judicial discretion. Errors of law, fact, and judgment drove every step of its reimagined analysis. Errors compounded errors. Given the ubiquity and magnitude of these blunders, Plaintiffs ask this Court to reinstate the MDL court's initial *Daubert* decision—as briefed in *Gareis*—and reverse the reconsideration decision. This Court should also reverse the MDL court's erroneous orders granting summary judgment, precluding discovery, and sealing judicial records.

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CERTIFICATE OF BRIEF LENGTH

The undersigned counsel for Plaintiffs-Appellants certifies that this brief complies with the requirements of FED. R. APP. P. 32(a)(7)(B) in that it is printed in 14 point, proportionately spaced typeface utilizing Microsoft Word 2016 and contains 7,484 words, including headings, footnotes, and quotations.

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The undersigned counsel for Plaintiffs-Appellants, hereby certifies under 8th CIR. R. 28A(h)(2) that the brief and addendum have been scanned for computer viruses and that the brief and addendum are virus free.

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CERTIFICATE OF SERVICE

The undersigned counsel for Plaintiffs-Appellants, hereby certifies that on September 17, 2020, she electronically filed the Reply Brief and Supplemental Appendix of Plaintiffs-Appellants, with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the CM/ECF system. She certifies that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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